SURGICRAFT

# 510 (k) Summary – K072415

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|---|---|---|
| A | 510(k) Owner | Surgicraft Limited<br>16 The Oaks<br>Clews Road<br>Redditch, Worchester<br>England B98 7ST |
| | Contact | Donald W. Guthner<br>Orgenix, LLC<br>111 Hill Road<br>Douglassville, PA 19518<br>(646) 460-2984<br>(484) 363-5879 (FAX)<br>dg@orgenix.com |
| | Preparation Date | December 7, 2007 |
| B | Trade Name | STALIF™ C |
| | Common Name | Intervertebral Body Fusion Device, IBF Device |
| | Classification Name | Intervertebral Body Fusion Device |
| C | Predicate Device(s) | Substantial equivalence for the *Surgicraft STALIF™ C* is based on its similarities in indications for use, design features, operational principles and material composition when compared to the predicate devices cleared under the following submissions:<br>• P980048 S003 BAK/C Vista Cervical Interbody Fusion Device, Zimmer Spine, USA<br>• P000028 AFFINITY Anterior Cervical Cage System, Medtronic Sofamor Danek, USA<br>• K071833 Mosaic Device (a PEEK Cervical IBF device), Spinal Elements, Inc. |

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| D | Device Description | STALIF™ C is a radiolucent intervertebral body fusion device and unicortical cancellous bone screws and is intended to be used as an IBF cage without supplementary fixation. The cross section profile of the STALIF™ C is similar to that of the vertebral body endplate with a central cavity that can be packed with autograft. STALIF™ C is manufactured from PEEK-Optima$^{R}$ LT1. |
| E | Intended Use | The STALIF C is intended to be used as an intervertebral body fusion cage as a stand alone system used with the bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space from levels C2 to T1 for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone to facilitate fusion. STALIF$^{TM}$ C is intended to be used at one level.<br>The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage. |
| F | Technological Characteristics | As was established in this submission, the subject device is substantially equivalent to other devices cleared by the agency for commercial distribution in the United States.<br><br>Engineering drawings, labeling, and mechanical testing have demonstrated that the subject device is substantially equivalent, if not identical, to its predicate devices in terms of design, materials of composition, indications for use, and such other characteristics as may be associated with the manufacture of any medical device. |
| G | Non-Clinical Testing | FDA Recognized Performance Standards<br>♦ ASTM 2077-03<br>♦ ASTM F2267-04<br>♦ ASTM F1877-98(03) |
| H | Clinical Testing | Not applicable to this device |
| I | Conclusions | Based on the 510(k) Summary and the information provided herein, we conclude that the *Surgicraft STALIF™ C* is substantially equivalent to the existing legally marketed devices under the Federal Food, Drug and Cosmetic Act. |
| J | Additional Information | NA |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Surgicraft, Ltd
% Orgenix, LLC
Mr. Donald Guthner
111 Hill Road
Douglassville, PA 19518

SEP 12 2011

Re: K072415
Trade/Device Name: STALIF™ C
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: December 17, 2007
Received: December 19, 2007

Dear Mr. Guthner:

This letter corrects our substantially equivalent letter of January 25, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): _____

Device Name: STALIF™ C

Indications for Use:

The STALIF C is intended to be used as an intervertebral body fusion cage as a stand alone system used with the bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space from levels C2 to T1 for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone to facilitate fusion. STALIF™ C is intended to be used at one level.

The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

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